

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-2 and 6-40 are pending. The amendments are supported by the original disclosure and, thus, no new matter has been added.

Claim 1 is amended to specify that the herpes virus is a herpes simplex virus (HSV) and to delete the recitation of functional equivalents. Claim 1 is also amended to specify that HSV lacks a functional ICP34.5 gene. Support for this amendment may be found, for example, at page 6, lines 11-13, of the specification. The recitation that the virus has a functional UL43 gene is deleted from claim 1 because this limitation is not an essential feature of the invention as indicated at page 3, line 8, of the specification.

Claims 3-5 are cancelled without prejudice or disclaimer.

The dependencies of claims 7-8, 10-11 and 15-16 is corrected.

Claim 9 is amended to provide polypeptides relevant to tumor cells. Claim 11 is amended to additionally specify all polypeptides of parasitic, viral or bacterial origin.

New claims 17-40 are added. New claim 17 is supported at page 15, lines 10-12, of the specification. New claim 18 is supported at page 15, lines 12-15, of the specification. Claims 19-29 correspond to claims 1-2, 6-7, 9, 11, 13 and 15-18 but further require that HSV lacks a functional UL43 gene. Support for HSV lacking a functional UL43 gene may be found, for example, at page 3, line 8, of the specification and in U.S. Pat. Appln. No. 09/833,073 which was incorporated by reference in the present continuation in-part application.

Claims 30-40 correspond to claims 1-2, 6-7, 9, 11, 13 and 15-18 but further require that the HSV comprises a functional UL43 gene. Support for an HSV comprising a functional UL43 gene may be found, for example, at page 4, line 7, of the specification.

The amendments are being made solely to advance prosecution of this application to allowance and do not constitute acquiescence, abandonment, or disclaimer with respect to any subject matter originally claimed. Applicant reserves the right to pursue any excluded subject matter by way of one or more further applications.

35 U.S.C. 112 – Definiteness

Claims 1-16 were rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicant traverses.

In claim 1, the phrase "such that dendritic cells are infected with said virus" has been deleted. It is, therefore, now clear that any form of administration may be used in the claimed method.

Applicant requests withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 1-16 were rejected under Section 112, first paragraph, because it was alleged that the specification "while being enabling for a method involving *ex vivo* infection of dendritic cells, does not reasonably provide enablement for *in vivo* infection of dendritic cells." Applicant traverses.

As amended, amended claim 1 no longer refers specifically to the infection of dendritic cells. The Examiner has acknowledged that those skilled in the art would be aware of routine methods of administering herpes simplex virus to a subject in a manner effective to obtain an immune response. The claimed method does not require infection of dendritic cells. Thus, claim 1, dependent claims 2 and 6-18, new independent claims 19, and new dependent claims 20-29 are enabled by the specification.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because it would not require undue experimentation for a person of skill in the art to make and use the claimed invention.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. Obviousness can only be established by combining or modifying the prior art teachings to produce the claimed invention if there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to a person of ordinary skill in the art. See, e.g., *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992). It is well established that the mere fact that references can be combined does not render the resultant combination obvious unless the desirability of that combination is also taught or suggested by the prior art. See *In re Mills*, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). Thus, even if all elements of the claimed invention were known, this is not sufficient by itself to establish a prima facie case of obviousness without some evidence that one would have been motivated to combine those teachings in the manner proposed by the Examiner. See *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (B.P.A.I. 1993).

Claims 1-16 were rejected under Section 103(a) as allegedly unpatentable over Krisky et al. (Gene Therapy 5:1517-1530, 1998) or Glorioso et al. (U.S. Patent 5,998,174). Applicant traverses.

Claim 1 is amended to specify that the attenuated herpes simplex virus lacks a functional gene encoding ICP34.5. Neither Krisky et al. nor Glorioso et al. teach or suggest a herpes simplex virus which lacks a functional gene encoding ICP34.5 in addition to lacking a functional vhs gene and a functional gene encoding ICP47. The same limitation is present in new independent claims 19 and 30. Claims 1, 19 and 30 are therefore not obvious over Krisky et al. or Glorioso et al. Claims 2-16 are all dependent on claim 1, claims 20-29 are all dependent on claim 19, and claims 31-40 are all

dependent on claim 30. Accordingly, these claims are also not obvious over the cited references.

Withdrawal of the Section 103 rejection is requested because the invention as claimed would not have been obvious to a person of ordinary skill in the art at the time it was made.

Double Patenting

Claims 1-16 are rejected under the judicially-created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-23 of U.S. Patent 6,713,067. Applicant traverses because of the terminal disclaimer submitted herewith.

It should be noted that the filing of a terminal disclaimer to overcome a rejection based on non-statutory double patenting is not an admission that the rejection was proper. See *Quad Environmental Technologies Corp. v. Union Sanitary District*, 20 USPQ2d 1392, 1394-95 (Fed. Cir. 1991). The Court stated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection." Thus, submission of a terminal disclaimer is not an admission that the pending claims are obvious over the claims of U.S. Patent 6,713,067.

Claims 1-16 are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-19 of co-pending Application No. 10/273,348. Applicant traverses.

Claim 1 is amended to specify that the herpes simplex virus lacks a functional ICP34.5 gene. This limitation is not required by claims 1-23 of co-pending Application No. 10/273,348 which require that the herpes simplex virus is incapable of expressing a substantial amount of functional ICP22 in mammalian dendritic cells. This limitation is not an essential feature of the claims of the present application. Therefore, the claims of the present application are patentably distinct over claims 1-19 of co-pending Application No. 10/273,348.

Withdrawal of the obviousness-type double-patenting rejections is requested because the allegedly conflicting claims are patentably distinct from the instant claims.


Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicant submits that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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